

REMARKS

Claims 1-16 are pending in the present application. In this response, claims 1 and 16 have been amended for clarity and to improve claim form. No claims have been cancelled or added. Accordingly, claims 1-16 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections – 35 USC § 102

Claims 1, 3-7, and 16 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent Application 2003/0013985 to Vahid Saadat (Saadat). Specifically, the Office states that Saadat teaches the features of claim 1 by referencing Fig. 6 and its corresponding description of an introducer (370) and elongate tubular member (372), and by referencing paragraph 27, lines 1-5, which describes Fig. 1, for its alleged disclosure of the shape imparting element imparting a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer.

Applicants disagree with this rejection. Claims 1 and 16 of the present application recite that the elongate, shape imparting element *is received in the at least one lumen of the tubular member* and, further, that *the shape-imparting element impart[s] a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer*. Saadat fails to disclose one or both of these features in the variations shown in Fig. 1 and Fig. 6.

With respect to Fig. 1, the tubular member could be either catheter (18) or hollow guidewire (20). If it is assumed that the catheter (18) is the tubular member, then hollow guidewire (20) would be the shape-imparting element. However, the hollow guidewire (20) does not impart a predetermined shape to the distal end of the tubular member, as claimed. This is because catheter (18) is withdrawn such that guidewire (20) emerges from the distal end of the catheter (18) to revert

to its looped configuration within the blood vessel (see paragraph 27 of Saadat). Thus, guidewire (20) does not impart a shape to anything.

On the other hand, if it is assumed that the hollow guidewire (20) is the tubular member, then temperature probe (23) (Fig. 2), which is received within the at least one lumen of the tubular member, would be the shape-imparting element. Here however, temperature probe (23) does not impart a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer, as claimed. This is because temperature probe (23) has such flexibility that it “follows the curves of helical loops (26) of guidewire (20) without forcing guidewire (20) to become straight (see paragraph 23 of Saadat). Thus, the temperature probe (23) does not impart any shape to the guidewire (20) or any other element.

With respect to Fig. 6, the Office has named guidewire (320) as the shape-imparting element. However, guidewire (320) is not received in at least one lumen of tubular member (372), as claimed. Rather, the guidewire (320) is externally arranged about tubular member (372) and a portion of introducer (370). Given that it is external to tubular member (372), guidewire (20) also cannot impart a predetermined shape to the distal end of the tubular member, as claimed. Accordingly, there is no shape imparting element in the variation illustrated in Fig. 6.

In another aspect, Saadat fails to teach a distal end of the shape-imparting element being anchored proximally a distal end of the introducer, as claimed. The Office cites paragraph 40, lines 7-10 (Fig. 6) as describing this feature. However, Applicants submit that in view of this description, the shape-imparting element here may not be fixed at all. According to paragraph 40, lines 1-4, the hollow guidewire (320) is received within the lumen of first portion (370) via an aperture (374). Thus, there is no clear disclosure about whether the guidewire is fixed or anchored after passage through the aperture.

In view of the above, withdrawal of the rejection under 35 U.S.C. §102(b) of claims 1 and 16, and claims 3-7, which depend from claim 1, is respectfully requested.

Claim Rejections – 35 USC § 103

A. Claim 2 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Saadat in view of U.S. Patent 5,556,380 to Mark T. Ridinger et al. (Ridinger). Specifically, the Office states that Saadat does not teach a control mechanism which, in use, applies torsion to the shape imparting element to effect adjustment of the predetermined shape of the distal end of the tubular member. However, the Office further states that this would be obvious to one of skill in view of the teachings of Ridinger so that Saadat's loops could be adjusted to provide optimal organ contact.

Applicants disagree with this rejection. As discussed above, Saadat fails to disclose a shape-imparting element that imparts a predetermined shape to the distal end of the tubular member and a shape-imparting element that is anchored proximally a distal end of the introducer. Given that Ridinger does not cure these defects, it cannot be said that the claims are rendered obvious by this combination of references.

Withdrawal of the rejection of claim 2 under 35 U.S.C. §103(a) is respectfully requested.

B. Claims 8-15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Saadat in view of EP 0479435 to Mary Elizabeth Bush et al. (Bush). Specifically, the Office states that Saadat does not teach an assembly that has two introducers, each introducer having a tubular member associated with it, but that this would have been obvious to one of skill to include in view of the teachings of Bush.

Applicants disagree with this rejection. As discussed above, Saadat fails to disclose a shape-imparting element that imparts a predetermined shape to the distal end of the tubular member and a shape-imparting element that is anchored proximally a distal end of the introducer. Given that Bush does not cure these defects, it cannot be said that the claims are rendered obvious by this combination of references.

Accordingly, withdrawal of the rejection of claims 8-15 under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 559022000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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